IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

DAVID REED, individually, and LINDA REED, individually, and as husband and wife,	)	
Plaintiffs,	)	
v.	)	No. CIV-06-917-C
SMITH & NEPHEW, INC., a Tennessee corporation,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs filed this diversity action against Defendant alleging manufacturers' products liability, breach of warranty, and failure to warn regarding an allegedly defective femoral implant surgically implanted into Plaintiff David Reed. Myriad motions have been filed in this case. First, Defendant has filed a motion to exclude the testimony of Plaintiffs' expert. (See Def.'s Mot. to Exclude, Dkt. Nos. 55 & 57). Plaintiffs have responded (see Pls.' Resp., Dkt. No. 66), and Defendant has filed a reply (see Def.'s Reply, Dkt. No. 72). Second, Plaintiffs have filed a motion to exclude the testimony of Defendant's experts (see Pls.' Mot. to Exclude, Dkt. No. 56), to which Defendant has responded (see Def.'s Resp., Dkt. No. 63); Plaintiffs have filed a reply (see Pls.' Reply, Dkt. No. 77). Third, Defendant filed a motion for summary judgment and brief in support (Def.'s Mot. for Summ. J., Dkt. Nos. 59 & 60). Plaintiffs have responded (Pls.' Resp. to Mot. for Summ. J., Dkt. No. 65), and Defendant has filed a reply (Def.'s Reply to Pls.' Resp. to Mot. for Summ. J., Dkt. No. 71.). Fourth, Plaintiffs filed a motion to strike Defendant's supporting affidavits (see Pls.'

Mot. to Strike, Dkt. No. 67). Before Defendant responded (see Def.'s Resp. to Mot. to Strike, Dkt. No. 78), Plaintiffs filed a second motion to strike the supporting affidavits in Defendant's response to the motion to exclude (See Pls.' Second Mot. to Strike, Dkt. No. 75),[1] and they since have also filed a reply to Defendant's response to the first motion to strike (see Pls.' Reply to Def.'s Resp. to Mot. to Strike, Dkt. No. 87). Defendant then filed a response to Plaintiffs' second motion to strike (see Def.'s Resp. to Second Mot. to Strike, Dkt. No. 91).

Because Plaintiffs rely on their expert witness's testimony in opposition to summary judgment, and Defendant relies on its expert opinions both in its motion for summary judgment and to exclude the testimony of Plaintiffs' expert, the Court first will examine the motions regarding exclusion of both parties' experts. Cf. 103 Investors I, L.P. v. Square D Co., 470 F.3d 985, 987, 991 (10th Cir. 2006) (finding no error when district court granted summary judgment as plaintiff had produced no evidence, beyond expert testimony that was inadmissible, that demonstrated a genuine issue of material fact); Mitchell v. Gencorp Inc., 165 F.3d 778, 780 (10th Cir. 1999) ("Where a trial court excludes evidence essential to maintain a cause of action, the propriety of summary judgment depends . . . entirely on the evidentiary ruling." (internal quotation marks omitted)).

[1] Plaintiffs' reply in support of their motion to exclude the testimony of Defendant's experts also contains a "Brief in Support of Plaintiffs' Second Motion to Strike Defendant's Supporting Affidavits." (See Pls.' Reply, Dkt. No. 77.)

I. BACKGROUND

Much of the relevant factual background relating to Plaintiff David Reed ("Reed")'s medical history is undisputed. Reed has been receiving treatment for avascular necrosis[2] since at least 1980, when he received his first total right hip replacement at the age of thirty. (Reed Dep., Def.'s Mot. for Summ. J. Ex. 1, at 13, 16.) At the time of this first surgery, it was Reed's belief that there were no alternatives to having his hip replaced with an artificial component, although he was relatively young to require such treatment. (Id. at 16.) Reed was informed at that time that there was a likelihood he would have multiple hip surgeries over the course of his life. (Id.) Reed had success with this initial device until 1991, when loosening of the acetabular component (the cup portion in which the ball at the top of the hip implant rotates) was noted. Surgery was then performed to replace only the acetabular component portion of the implant. (Reed Record, Def.'s Mot. for Summ. J. Ex. 2, at OA-00006.)

Reed reported progressive loosening of the implant from 1991 on. (Id. at OA-00014.) In January 1994, Reed sought treatment for problems with his right hip, including hip pain extending down to his right knee. (Tkach Record, Def.'s Mot. for Summ. J. Ex. 3.) X-rays taken at that time indicated that although the acetabular component appeared to be fitting well, there was "mild femoral loosening along the proximal femoral stem" that appeared to

[2] Avascular necrosis is "necrosis of bone tissue due to impaired or disrupted blood supply . . . marked by severe pain in the affected region and by weakened bone that may flatten and collapse." Necrosis is death of living tissue. Merriam-Webster's Medical Dictionary, http://medical.merriam-webster.com (2005).

be new, "possible early loosening of [the] femoral component." (Id.) By January 2001, Reed complained that the implant hurt all the time, cracked, rattled, and felt unstable; he was forced to use crutches at times and was limping. (Reed Record at OA-00014.) At that time Reed's physician concluded that the implant was loose both in the femoral and acetabular components and that Reed had "osteolysis laterally and some medially."[3] (See id.)

Reed underwent revision surgery by Dr. Steven Davenport on January 30, 2001, to replace the entire hip implant.[4] Dr. Davenport replaced Reed's old hip implant with a 260 mm Echelon Porous Bowed Femoral Component, size 13, which has been in continuous production and marketing since 1997. (Def.'s Mot. for Summ. J. at 8; Pls.' Resp. to Mot. for Summ. J. at 3.) While Dr. Davenport was taking the old component out, Reed's greater trochanter broke.[5] (Davenport Dep., Def.'s Mot. for Summ. J. Ex. 5, at 15-16.) After positioning the new component, Dr. Davenport attempted to wire Reed's greater trochanter and proximal femur back together, in order to hold the greater trochanter in position and "snug everything back down to the component." (Id. at 16, 25.)

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[3] Osteolysis is the dissolution of bone. Lateral means of or relating to the side or lying away from the median axis of the body, and medial means lying or extending toward the middle or median axis of the body. Merriam-Webster's Medical Dictionary, supra note 2.

[4] Because Reed's January 2001 surgery was performed to replace a failed component implanted in a previous surgery, it is referred to as a "revision" surgery, in contrast to Reed's "primary" surgery to initially implant his hip replacement in 1980. (Reed Record at OA-00006); Merriam-Webster's Medical Dictionary, supra note 2.

[5] Dr. Davenport describes the greater trochanter as "the outside or the lateral portion of the femur, where the big muscles attach to move the hip." (Davenport Dep. at 16.)

Although Reed was limited to non-weight-bearing activities following the surgery (see Reed Record at OA-00006), by the time Reed visited Dr. Davenport on February 13, 2001, the wire on his greater trochanter had been pulled off, and his greater trochanter had pulled away from his femur. (See id. at OA-00007; Davenport Dep. at 29-30.) By March 13, 2001, Reed was unable to stand on his right leg unassisted, and his greater trochanter had avulsed, or pulled away, from his femur.[6] (Davenport Dep. at 30; Reed Record at OA-00007.) On May 9, 2001, Dr. Davenport performed a repair of Reed's greater trocherantic avulsion fracture by pulling the greater trochanter back down toward the proximal femur and then wiring it with a cable grip system as well as performing a bone graft. (Reed Record at OA-00007 to -08.) Although it would have been preferable to set the greater trochanter up against the proximal femur for the bones to heal, Dr. Davenport was physically unable to pull the bone down that far and so a gap existed even after the surgery. Reed's implant, however, remained in a satisfactory position. (Id.; Davenport Dep. at 35-36.)

Following the May 2001 repair of the avulsion fracture of his greater trochanter, Reed had several follow-up visits where he reported that his pain and his limp had subsided; Reed stated that he was pleased with the solidness of the implant following the repair surgery, although Dr. Davenport noted that his greater trochanter had possibly slipped a millimeter or two. (Reed Record at OA-000008.) In November 2002, Reed consulted Dr. Davenport

[6] An avulsion fracture is the detachment of a bone fragment that results from the pulling away of a ligament, tendon, or joint capsule from its point of attachment on a bone. Merriam-Webster's Medical Dictionary, supra note 2.

and reported several days of pain in his hip. After prescribing bone scans, Dr. Davenport reported that the femoral component looked "pretty solid," Reed had a "little bit of uptake" in his pelvic region, and that his pain may be due to barometric changes. (Id. at OA-00008 to -11.)

Dr. Davenport did not see Reed again until September 21, 2005, when Reed came in complaining of pain. (Id. at OA-00011.) Reed's implant had fractured around the shoulder area, although the distal portion holding it into his femur was well fixed. (Id.; Davenport Dep. at 48.) Dr. Davenport determined that it would be necessary to replace the entire prosthesis and that he would have to split Reed's femur to remove the broken component. (Reed Record at OA-00011; Davenport Dep. at 48.) Dr. Davenport diagnosed Reed with "[m]echanical failure of a right total hip arthroplasty, specifically a broken right femoral stem." (See Reed Record at OA-00026.) On October 10, 2005, Dr. Davenport performed revision surgery on Reed. Dr. Davenport reported that the proximal (top) portion of the implant was removed without difficulty, as it had not ingrown, but that the distal (bottom) portion inserted into the femur was well fixed with bony ingrowth. (Id. at OA-00025 to -26.) When Dr. Davenport attempted to remove the distal portion of the stem, he "ended up fracturing it as it was completely ingrown all the way through." (Id. at OA-00025.) Dr. Davenport implanted another Echelon implant, this time a size 17 rather than a 13 for the best possible stability following removal of the old implant, and he also performed some metal plating and bone grafting. (Id.) There is nothing in the record regarding Reed's experience with the size 17 implant since its implantation in October 2005.

II. DEFENDANT'S MOTIONS

A. Defendant's Motion to Exclude Testimony of Plaintiffs' Expert

1. Standard

Plaintiffs have named William Coleman, a consulting metallurgical engineer, as their expert witness in chief. (See Dkt. No. 26.) Defendant asserts that Coleman's proposed expert testimony should be excluded because it fails to satisfy the standards of Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), and Fed. R. Evid. 702. The admissibility of expert testimony is governed by Rule 702:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Pursuant to Rule 702 and Daubert, the Court has

> a gatekeeper obligation to ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. Fulfilling the gatekeeper duty requires the judge to assess the reasoning and methodology underlying the expert's opinion and determine whether it is both scientifically valid and applicable to a particular set of facts. The Supreme Court has made clear that where [expert] testimony's factual basis, data, principles, methods, or their application are called sufficiently into question . . . the trial judge must determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline.

Goebel v. Denver & Rio Grande W. R.R. Co., 346 F.3d 987, 991 (10th Cir. 2003) (alterations in original) (citations and internal quotation marks omitted).

In making a reliability determination, the Court may consider whether the opinion at issue can be or has been tested or subjected to peer review, the rate of error, the existence of standards controlling the technique, and the general acceptance of the methodology in the relevant scientific community. See Daubert, 509 U.S. at 593-94. None of these, or other factors that might be considered, are determinative. Fed. R. Evid. 702 advisory committee's note; see also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150-51 (1999). As the proponent of their expert witness's testimony, Plaintiffs have the burden of establishing its admissibility. Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 n.4 (10th Cir. 2001).

2. Discussion

Plaintiffs submitted that Coleman would testify as to "the design and manufacture" of the Echelon hip implant. (See Dkt. No. 26.) Coleman examined the failed implant with the assistance of micrographs, scanning electron microscope, and x-rays, and he also performed destructive testing and additional analysis on the implant. (See Coleman Report, Dkt. No. 36 Ex. 1; Coleman Supplemental Report, Dkt. No. 36 Ex. 2.) Coleman's Rule 26 report and supplemental report indicate that Coleman proposes to testify, within the disciplines of metallurgical, mechanical, and general engineering, that: the Echelon hip implant failed as a result of fatigue fracture under repeated load cycling, although the implant's selection was consistent with the manufacturer's guidelines and there was adequate bone in-growth and adhesion; the implant was unfit for its intended purpose; study of the failed implant revealed the presence of microcracks and inherent flaws which provided

multiple sites for fatigue cracking; such fatigue cracking commenced early in the lifetime of the implant; and an advanced crack network above the primary fracture adversely affected the implant's resistance to fatigue cracking, induced premature failure, and constituted a defective condition. (See Coleman Report at 7-8; Coleman Supplemental Report at 3, 6-7.) Coleman ultimately concluded that "[f]ailure was caused by defects in the sintered coating/substrate interface, its likelihood enhanced by the unfavorable microstructure. On this basis the device is defective." (Coleman Supplemental Report at 7.)

a. Qualification To Testify

Defendant presents several arguments to support exclusion of Coleman's proposed testimony. First, Defendant asserts that for purposes of the Court's initial determination of "whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline," Coleman does not have expertise in the relevant disciplines of biomaterials, biomechanics, and orthopedic implant design. (Def.'s Mot. to Exclude, Dkt. No. 57, at 3, 5 (quoting Kumho Tire Co., 526 U.S. at 149 (alteration in original)).) While there is no dispute as to whether Coleman is qualified to testify as a metallurgical engineer, according to Defendant's experts,[7] Coleman is not qualified to testify regarding Reed's failed implant without knowledge of these other scientific disciplines.[8]

[7] The Court recognizes that Plaintiffs likewise have moved to exclude the testimony of Defendant's experts, and Plaintiffs' expert's qualifications are examined in light of the Court's ruling on that motion, which is discussed below.

[8] Metallurgy is defined as the science and technology of metals. Biomaterials are natural or synthetic materials suitable for introduction into living tissue especially as part of medical devices, such as artificial joints. Biomechanics is the scientific study of the mechanics of biological,

In simplest terms, Coleman is proposing to testify that the implant failed due to fatigue cracking caused by repeated load cycling combined with internal defects in the form of microcracks and an advanced crack network. Defendant, however, is essentially arguing that the implant failed due to lack of sufficient bone support from Reed's body. (See Def.'s Mot. for Summ. J., Dkt. No. 59, at 14.) Having carefully reviewed Coleman's expert reports and deposition testimony, it is clear that Coleman's conclusions are based upon his observation of metallurgical flaws within the implant. Coleman does not attempt to delve into the fields of biomaterials or biomechanics, except to note his opinion that the fracture was not caused solely by stresses from the patient's body or medical reasons, which simply hastened a failure caused by "the defects in the material and the defects in the device." (Coleman Dep., Def.'s Mot. to Exclude Ex. 3, at 80.) In regards to his knowledge of orthopedic implants, Coleman testified that he has taught classes in material selection and failure analysis that included case studies of implant failures and implant design. (Id. at 7.) Further, Coleman is not purporting to be an expert in medical device design, but rather giving his opinion, based on intensive examination and testing, on why the device implanted into Reed failed. Indeed, at least one federal district court has indicated that a metallurgist who has tested the failed device and studied comparable devices may be the optimum witness regarding causation of a hip implant failure. See Benedict v. Zimmer, Inc., 405 F. Supp. 2d 1026, 1035 (N.D. Ia. 2005) (noting in excluding implanting surgeon's testimony regarding existence of a defect and causation

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especially muscular, activity. Merriam-Webster's Online Dictionary, http://merriam-webster.com/dictionary (2005).

that the orthopedic surgeon "is not a metallurgist, has not conducted any testing on the device, and has not read any published reports on fatigue or failure rates of comparable devices"). Plaintiffs have established that Coleman is qualified to testify as to his opinion that the device failed due to internal structural flaws and regarding the basis for that opinion.

b. Reliability of Testimony: Methodology

Defendant next argues that while Coleman identified the correct methodology to use in reaching his conclusions, his analysis deviated substantially from that methodology. (Def.'s Mot. to Exclude at 9.) First, Defendant claims that in his x-ray analysis Coleman should have carefully examined Reed's x-rays, but instead only "glanced" at them. According to Defendant, if Coleman had studied the x-rays more thoroughly, Coleman would have reached the same conclusion as Defendant's expert, namely, that the component already fully fractured prior to removal. (Id.) Coleman instead testified that after viewing the x-rays as well as the surgeon's notes,[9] he interpreted them as indicating that the implant had not fractured all the way through until Dr. Davenport attempted to remove it from Reed's body. (Coleman Dep. at 72-73.)

Regarding Coleman's testimony about the x-rays and Dr. Davenport's notes, although the Court should focus on an expert's methodology rather than the conclusions it generates, Daubert, 509 U.S. at 595, Defendant's questions regarding the basis for Coleman's opinions

[9] Coleman's deposition testimony referred to both the x-rays and Dr. Davenport's operative report stating that Dr. Davenport "attempted to get the [distal portion of the] stem out; however, [he] ended up fracturing it as it was completely ingrown all the way through." (Reed Record at OA-00025.)

in reality attack only the extent, not the methodology itself, of Coleman's analysis. "[U]nder Daubert, a disagreement with the expert's conclusion is not grounds for exclusion." See North v. Ford Motor Co., 505 F. Supp. 2d 1113, 1118 (D. Utah 2007). Defendant mischaracterizes Coleman's testimony by claiming that the expert "disregard[ed]" the x-rays. (Def.'s Reply at 4.) While Coleman allowed that the x-rays were "not something [he] spent much time with," Coleman further testified that he had "seen" the x-rays , tried "to get a picture . . . of what had happened," and did not feel there was anything in the x-rays that was significant to his opinion. (Compare id. with Coleman Dep. at 67-68, 73.) Moreover, as Plaintiffs point out, Defendant has not adequately demonstrated how Coleman's allegedly erroneous level of scrutiny of the x-rays affected Coleman's conclusions based on examination and testing of the implant. (Pls.' Resp. at 6.) Defendant's questions are more appropriate for contemporaneous objection and/or cross-examination than as grounds for exclusion of testimony. See Goebel, 346 F.3d at 994 ("[The] court is [not] in a position to declare or even to know with any degree of certainty whether otherwise admissible expert testimony is, in fact, correct. 'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" (quoting Daubert, 509 U.S. at 596)). It is only when there is "too great an analytical gap between the data and the opinion proffered" that the expert's opinion should be excluded based on the conclusions drawn. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Defendant has not shown that there was

an "absolute" or significant failure by Coleman to follow appropriate methodology or that Coleman's testimony in this area should be excluded. (See Def.'s Mot. to Exclude at 10.)

Next, Defendant submitted an affidavit from its expert David Kelman, a metallurgical engineer, outlining Kelman's belief that Coleman's application of the methodology used for interpreting hardness data and preparing samples for analysis was erroneous. (See Kelman Aug. 14, 2007, Aff., Def.'s Mot. to Exclude Ex. 1, ¶¶ 22-28.)[10] While Defendant does not dispute that the chosen methodology was acceptable, Defendant's expert Kelman claims that Coleman's analysis deviated substantially from the methods that Coleman purported to apply. According to Defendant,

> Coleman interprets the hardness data by attempting to convert values to the tensile strength of the material, thereby showing a big difference and broad range of numbers. That result occurred because he incorrectly used the conversion tables for nonaustenitic steels, which are not relevant to the alloy used in this case.

(Def.'s Mot. to Exclude at 9.) Defendant further argues that "[u]sing the wrong hardness values led [Coleman] to the erroneous conclusion that there was a significant and wide variance in the testing values, which simply did not exist."[11] (Def.'s Reply at 4.)

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[10] As discussed below, paragraph 29 of Kelman's affidavit is stricken from consideration.

[11] Although it is unclear from Defendant's motion precisely what portion of Coleman's testimony is disputed, Defendant's objection presumably is referring to Coleman's opinion that based on the average hardness of the stem, "accepted conversion tables indicate that this hardness level corresponds to a tensile strength of about 125,00 psi" – the allegedly incorrect conversion tables. This conclusion seemingly is a basis for Coleman's testimony that "the grain structure at the surface is vastly different than the grain structure in the middle of the rod, the stem," "[t]he stark contrast in grain size is a consequence of localized recrystallization during the sintering process," and "[d]ifferent grain structures equate to varying mechanical properties" – the "big difference and broad range of numbers." (See Coleman Supplemental Report at 2, 3; Coleman Dep. at 84-85.)

Defendant relies on Kelman's expert affidavit for this proposition. Kelman's affidavit, however, noted that Kelman's belief that "[Coleman] apparently incorrectly used" the wrong conversion tables, not that he unquestionably used the wrong tables. (Kelman Aug. 14, 2007, Aff. ¶ 23 (emphasis added).) While Defendant's experts are free to critique Plaintiffs' expert and readily have done so, Defendant merely has presented conjecture that Coleman used the incorrect conversion tables and has not demonstrated to the Court, beyond "apparently," that Coleman improperly applied an accepted methodology. Again, Defendant's argument really lies in the difference between experts' final conclusions: Coleman's conclusion that there was a broad range of mechanical properties within the sample versus Kelman's conclusion that there were only "minimal differences." (Compare id. with Coleman Supplemental Report at 2-3.) Because Defendant has not demonstrated that any step of Coleman's rendered his analysis unreliable and thus his testimony inadmissible, see Mitchell, 165 F.3d at 782, Coleman will be allowed to testify regarding his interpretation of the hardness data, subject to cross-examination by Defendant.

Finally, Defendant asserts that while Coleman identified a correct methodology, the Medlin process,[12] for preparing testing samples for analysis, "he failed to use that methodology in multiple and significant respects." (See Def.'s Mot. to Exclude at 9; Kelman

[12] According to Kelman, Coleman correctly identified the methodology cited in Medlin et al., Metallographic Preparation of Orthopedic Medical Devices, reprinted in Medical Device Materials II (Proceedings of Materials and Processes for Medical Devices 2004) 73 (2005). Although Coleman cited this article in his Rule 26 supplemental report, the Court was unable to locate a copy and is relying on the parties' representations as to the methodology outlined in the article.

Aug. 14, 2007, Aff. ¶ 25.) Defendant's expert Kelman opines that Coleman's failure to prepare the specimens according to the Medlin technique "artificially resulted in conditions that Coleman misinterpreted as cracking and potential defects" and resulted in "distorted images which were not useful for analysis." (Def.'s Reply at 4; Kelman Aug. 14, 2007, Aff. ¶ 25; Kelman Dep., Dkt. No. 72 Ex. 2, at 72-76, 189-91.) Specifically, Defendant claims that Coleman failed to produce a specimen without "incomplete fill," did not adequately preserve the edge surface for examination, over-etched the components, and that improper techniques left visible cuts on the surface of the samples. (Kelman Aug. 14, 2007 Aff., ¶ 25; Kelman Dep. at 72-76; 189-91.) Having reviewed Coleman's expert reports and deposition testimony, it is clear that Coleman believes that he did in fact utilize a proper methodology and that doing so led to reliable results. (See Coleman Supplemental Report at 2 ("The mounted section was prepared for microstructural study using standard metallographic techniques, but without subjecting the specimen to the rigors of coarse or fine grinding.").) Defendant's expert's argument is not based upon Coleman's description of his technique or by observing Coleman prepare the sample, but rather upon reviewing Coleman's microphotographs and the sample after Coleman had finished his analysis. (Kelman Dep. at 72-76, 189-91.) Thus, Kelman is arguing that Coleman must not have followed the Medlin technique based on what the sample looked like – possible visible saw cuts, e.g. – after Coleman completed his testing of the implant. Absent specific observations and comparisons, Kelman's contention leaves no room for the possibility that Coleman followed a proper methodology but the resulting specimen simply did not appear as Kelman had

expected it to. Again, the evidence does not show that Coleman took steps that rendered his analysis unreliable, and thus Plaintiffs have demonstrated the testimony's admissibility. See Mitchell, 165 F.3d at 782.

c. Testimony Contrary to Generally Accepted Scientific Principles

Finally, Defendant argues that Coleman's testimony is contrary to accepted principles in orthopedic implant design. (Def.'s Mot. to Exclude at 10, 13.) Under Rule 702 and Daubert, Plaintiffs "need not prove that the expert is undisputably correct or that the expert's theory is 'generally accepted' in the scientific community." Mitchell, 165 F.3d at 781. Rather, Plaintiffs must show that their expert used a scientifically sound method in reaching his conclusion and that the opinion is based on facts sufficiently reliable under Rule 702. Id. The Court will address Defendant's contentions one by one.[13]

First, Defendant argues that Coleman lacks knowledge about implants manufactured from the cobalt-chromium alloy used in Reed's implant and the effect of sintered coating and notching upon it. (See Def.'s Mot. to Exclude at 10.) Such knowledge is not confined within issues of orthopedic implant design, however, but encompasses a metallurgical issue regarding the characteristics of a certain metal alloy. As even Defendant concedes, Coleman is qualified to testify about metallurgical issues. Further, Coleman has experience in research and testing of cobalt-chrome alloys and on products bearing sintered coating. (See Coleman Dep., Dkt. No. 57 Ex. 3, at 24-29.) Therefore, Coleman may testify as to the characteristics

[13] The Court need not address several of Defendant's arguments because they are supported solely by now-stricken portions of their experts' affidavits, as discussed below.

of the metal used in the implant, including the effect of sintered coating on the metal and fatigue life of the implant. On a related note, Coleman is qualified to and may testify regarding his criticisms of the design's use of a sintered coating.

Next, Defendant objects to Coleman's testifying that in designing an implant, Coleman "would think all the foreseeable abnormalities and oddities of loading would be explored and would be underneath" the implant's design parameters, because "[t]here's so much done on hips and loads and gaits of different patients" and "[t]his is not a new product, not a new idea." (Id. at 100.) Defendant's expert Kelman counters that there have been only three investigations of actual loads on such implants and these types of studies largely are prevented by medical and ethical considerations. (Kelman Aug. 14, 2007, Aff. ¶ 27.) However, Coleman does not need to be an expert in pre-market design of orthopedic implants to be qualified to offer an opinion as to what testing he personally would recommend for metals used in an implant. While Coleman is not qualified to testify regarding the actual designing of an orthopedic implant, his opinion as to advisable load testing of implants and of the materials used in them is relevant to both material selection and failure analysis, which fall within his metallurgical engineering area of expertise. (See Coleman Dep. at 7.) Thus, this testimony of Coleman's shall be allowed, subject to cross-examination by Defendant.

III. PLAINTIFFS' MOTIONS

A. Jack Lemons, Ph.D.

Although the Court denied Defendant permission to add Jack Lemons, Ph.D., as an additional expert witness (see Order, Dkt. No. 45), Defendant has attached an affidavit and

extensive curriculum vitae from Lemons in support of its motion to exclude Coleman's testimony. "In short, [Lemons] is . . . an 'attack expert.'" Celebrity Cruises Inc. v. Essef Corp., 434 F. Supp. 2d 169, 190 (S.D.N.Y. 2006). Defendant argues that Lemons's evidence can be considered in connection with the pending motion to exclude the testimony of Plaintiffs' expert because Defendant does not intend to offer Lemons as an expert at trial, and the Court may consider evidence that would be inadmissible at trial in the context of such a Daubert proceeding. Plaintiffs assert, however, that Defendant had a duty to disclose Lemons pursuant to Fed. R. Civ. P. 26 and his testimony is subject to being prohibited under Fed. R. Civ. P. 37(c)(1).

Plaintiffs rightfully object to Defendant "submit[ting] a last-minute affidavit espousing the opinion of a previously undisclosed witness impugning Mr. Coleman's qualifications." (Pls.' Reply to Def.' Resp. to Mot. to Strike at 1.) The Court expressly rejected Defendant's request to add Lemons as an expert witness in this case, but Lemons's affidavit contains highly specialized opinions à la an expert report. Discovery in this case is now closed; Plaintiffs thus are prevented from deposing Lemons regarding his unanticipated opinion. Defendant is correct that the Court may consider inadmissible materials in regards to a Daubert motion. See Fed. R. Evid. 104(a); cf. Celebrity Cruises, 434 F. Supp. 2d at 190 (noting in examining a declaration in support of a Daubert motion made by an individual not proffered as an expert witness that the court "need only consider whether [the evidence] is sufficiently reliable to be persuasive in [the court's] evaluation of the expert reports that it criticizes"). Plaintiffs, however, are justified in their expectation

that Lemons's identity would have been disclosed under Fed. R. Civ. P. 26(a). Rule 26(a)(1)(A) requires a party to identify "each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses . . . identifying the subjects of the information," and the Rule contains no requirement that such individuals be presented at trial. Further, Rule 26(e)(1) requires that these initial disclosures be supplemented if "in some material respect the information disclosed is incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties." The identity of a de facto expert, whose testimony serves to contravene that of Plaintiffs' expert, is certainly information that Defendant has used "to support its claim[]" that Coleman's testimony should be excluded. See Fed. R. Civ. P. 26(a)(1).

Defendant has offered no substantial justification for failing to disclose Lemons and his testimony, and Plaintiffs clearly would be harmed by this unforeseen critique of their expert witness. Thus, Defendant shall not be "permitted to use as evidence . . . on [its] motion" this witness's affidavit, and it shall be stricken in its entirety. See Fed. R. Civ. P. 37(c)(1).

B. Dr. Glenn Landon

1. Plaintiffs' Motion to Exclude Dr. Landon's Testimony

Dr. Glenn Landon is an orthopedic surgeon retained by Defendant pursuant to Fed. R. Civ. P. 26(a)(2). Dr. Landon's Rule 26 expert report lists four paragraphs of conclusions regarding this case and Reed's hip problems, three of which state general information about femoral stem implants, the proper diameter to use, and the "well-known"

risk at the time of Reed's hip replacement "that a failure of the patient's bone to provide support for the implant may result in loosening, bending, cracking or fracture of the femoral stem." (See Landon Report, Dkt. No. 56 Ex. 2, at 2 paras. 1-2, 4.) The only paragraph in Dr. Landon's report that specifically pertains to Reed's surgery reads:

> At the time of David Reed's revision total hip arthroplasty on January 30, 2001, performed by Dr. Davenport, the patient's proximal femoral bone was of poor quality caused by extensive osteolysis around the long serviced cemented femoral component. The proximal bone loss with inadequate support of the femoral component [led] to post-operative complications and eventual fracture of the stem.

(Id. at 2 para. 3.)

Plaintiffs assert that Dr. Landon's proposed expert testimony should be excluded because it consists of "unsupported conclusions" that fail to satisfy the standards of Daubert and Rule 702. (Pls.' Mot. to Exclude at 1.) Specifically, Plaintiffs object to Dr. Landon's conclusion that the hip implant's fatigue fracture was due to Reed's "proximal bone loss with inadequate support of the femoral component," as Plaintiffs argue that the fatigue fracture was instead due to the hip implant being defective. (Compare id. at 2-3, 8 with Landon Report at 2 para. 3.) According to Dr. Landon, when Reed's bone at the upper end pulled away, it "put[] a great deal of extra stress on that upper part of the femoral stem," there was "enough [stress or load] to cause fracture," and the component, while fixed distally, just did not have sufficient support on top and eventually fatigue fracture resulted. (See Landon Dep., Dkt. No. 56 Ex. 1, at 55-56.)

Plaintiffs contend that Dr. Landon's opinion that the component broke due to lack of bone support is not based on facts that satisfy Rule 702's reliability requirements. According to Plaintiffs, Dr. Landon's deposition indicated that he could not testify exactly as to the amount of Reed's proximal bone loss in his femur, how much support was being given to the proximal end of the component, how much force would cause the component to break given Reed's anatomy, or whether there was a metallurgical or design defect in the implanted component. Thus, Plaintiffs argue, Dr. Landon's ultimate conclusion regarding the cause of the fracture is "sheer speculation," not sufficiently reliable under Daubert standards. (See Pls.' Mot. to Exclude at 2-3, 8 (citing Landon Dep. at 39, 42-46, 54-57).)

In response, Defendant attached a new affidavit by Dr. Landon, dated September 6, 2007, providing a much more detailed basis for his conclusion. (See Landon Sept. 6, 2007, Aff., Def.'s Resp. Ex. 1.) Plaintiffs in due course filed a motion to strike this new affidavit (see Pls.' Second Mot. to Strike, Dkt. No. 75) and a brief in support (Dkt. No. 77), to which Defendant filed a response (Def.'s Resp. to Second Mot. to Strike, Dkt. No. 91).

Having reviewed Dr. Landon's Rule 26 report, admissible portions of his affidavits, and deposition testimony, the Court has determined that Dr. Landon should be permitted to give his opinions that Reed's "proximal femoral bone was of poor quality caused by extensive osteolysis" at the time of his revision surgery on January 30, 2001, and that "proximal bone loss with inadequate support of the femoral component [led] to post-operative complications and eventual fracture of the stem." (See Landon Report at 2.) Although certain portions of his affidavit testimony will be stricken as discussed below, Dr.

Landon has demonstrated that he is qualified to testify as an expert in the field of orthopedic surgery, including orthopedic implant decisions, risks, and causation of device failure. As is clear from the extensive list of materials reviewed and his deposition testimony, Dr. Landon's opinions are based on sufficient facts or data and are the product of reliable principles and methods, pursuant to Rule 702.

2. Plaintiffs' Motion to Strike Dr. Landon's Affidavit of August 14, 2007

Plaintiffs' first motion to strike argues, inter alia, that Defendant has attached to its motion for summary judgment affidavits of its two expert witnesses in which their opinions extend beyond the scope of their Fed. R. Civ. P. 26 reports. (See Pls.' Mot. to Strike, Dkt. No. 67, at 1.) Plaintiffs argue that to the extent these affidavits express opinions not contained in the Rule 26 reports, they are improper and should be stricken.

Dr. Landon's August 14, 2007, affidavit is more extensive and also contains more information specific to Reed's case than what was contained in Dr. Landon's Rule 26 report. (See Landon Aug. 14, 2007, Aff., Def.'s Mot. for Summ. J. Ex. 20.) With respect to retained or specially employed experts from whom a report is required under Fed. R. Civ. P. 26(a)(2), Fed. R. Civ. P. 26(e)(1) imposes a continuing duty to supplement information contained in expert reports and in depositions if there are material additions or changes to what has been previously disclosed. Under Rule 37, "[a] party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial . . . or on a motion any witness or information not so disclosed." Fed. R. Civ. P. 37(c)(1); see also Jacobsen v. Deseret Book Co., 287 F.3d

936, 952-53 (10th Cir. 2002) (noting that in determining whether a Rule 26(a) violation is justified or harmless, the Court should consider: "(1) the prejudice or surprise to the party against whom the testimony is offered; (2) the ability of the party to cure the prejudice; (3) the extent to which introducing such testimony would disrupt the trial; and (4) the moving party's bad faith or willfulness" (internal quotation marks omitted)).

Having reviewed Dr. Landon's Rule 26 report, curriculum vitae, and his deposition testimony of June 12, 2007, it is clear that the sworn affidavit at issue does not differ in any material respect from the report and deposition testimony, which have both previously been disclosed to Plaintiffs. The affidavit is therefore proper and shall not be stricken from consideration. See Fed. R. Civ. P. 37(c)(1).

3. Plaintiffs' Motion to Strike Dr. Landon's Affidavit of September 6, 2007

In a separate motion, Plaintiffs similarly seek to strike an additional affidavit of Dr. Landon's, submitted by Defendant in response to Plaintiffs' motion to exclude Defendant's experts' testimony and dated September 6, 2007. (See Pls.' Second Mot. to Strike, Dkt. No. 75; Landon Sept. 6, 2007, Aff., Def.'s Resp. Ex. 1.) Having reviewed Dr. Landon's Rule 26 report, curriculum vitae, and his deposition testimony of June 12, 2007, it is clear that the sworn affidavit at issue consists almost exclusively of "additions or other changes" for which supplementation would have been required, see Fed. R. Civ. P. 26(e)(1).[14] Defendant has

[14] To the extent that a few sentences within both Dr. Landon's September 6, 2007, affidavit and Kelman's September 6, 2007, affidavit do no more than re-state content from their Rule 26 reports, deposition testimony, or the admissible portions of their earlier affidavits, striking the new affidavits is still appropriate because the content of those duplicative portions will be admissible based on their inclusion in the other submissions.

offered no substantial justification for the failure to supplement Dr. Landon's report or his deposition testimony, and Plaintiffs would be harmed by the admission of the previously undisclosed opinions. Therefore, Dr. Landon's affidavit dated September 6, 2007, is stricken in its entirety. Dr. Landon shall not be allowed to provide such testimony in support of Defendant's motions or responses, and the affidavit will not be considered or admitted at hearings or at trial. See Fed. R. Civ. P. 37(c)(1).

C. David Kelman

1. Plaintiffs' Motion to Exclude Kelman's Testimony

Plaintiffs make similar arguments regarding David Kelman, another of Defendant's expert witnesses for whom they provided a Rule 26 report. (See Kelman Report, Dkt. No. 38 Ex. C.) Kelman, a metallurgical engineer, is employed as Group Director of Product (Hip) Development for Defendant. Plaintiffs assert that Kelman's proposed expert testimony should be excluded because it fails to satisfy the reliability standards of Daubert and Rule 702. Plaintiffs also assert that Kelman lacks the necessary qualifications to be offered as an expert in metallurgy. (Pls.' Mot. to Exclude at 1.)

Specifically, Plaintiffs object to Kelman's conclusion that the fatigue failure of Reed's implant was the result of "excessive loading due to the loss of proximal bone, compromised benefit of adductor muscles due to the fracture of the greater trochanter, and the activity level of the patient." (See id. at 8; Kelman Report at 4.) Plaintiffs claim that Kelman's conclusion is not based on facts that satisfy Rule 702's reliability requirements. According to Plaintiffs, Kelman does not quantify the amount of Reed's bone loss, the additional stress caused by the

allegedly compromised adductor muscles, or the activity level of Reed Thus, Plaintiffs argue, Kelman's ultimate conclusion regarding the cause of the fracture is not sufficiently reliable under Daubert standards. (See Pls.' Mot. to Exclude at 8 (citing Kelman Dep. at 110-11).)

Having reviewed Kelman's Rule 26 report, admissible portions of his affidavits, and deposition testimony, the Court has determined that Kelman should be permitted to testify that Reed's hip implant's fatigue failure "was the result of excessive loading due to the loss of proximal bone, compromised benefit of adductor muscles due to the fracture of the greater trochanter, and the activity level of the patient." (See Kelman Report at 4.) Although certain portions of his affidavit testimony will not be allowed as discussed below, Kelman has demonstrated that he is qualified to testify as an expert in the field of medical implants, including device design and review of testing on the devices. As is clear from the extensive list of materials reviewed and his deposition testimony, Kelman's opinions are based on sufficient facts or data and are the product of reliable principles and methods, pursuant to Rule 702.

Plaintiffs additionally argue that Kelman's opinions offered to dispute those of Plaintiffs' expert metallurgist are inadmissible, partly because Kelman stated in his deposition that his knowledge of metallurgy is "fuzzy." (See Pls.' Mot. to Exclude at 9-10.)

> A: [O]ver the last several years I've spent more time on design side than on the materials side. . . .
> Q: And when you say the "materials side," are you referring to the stability of the material, the quality of the material?
> A: Metallurgical aspects, corrosion, things of nature.

> Q: Are you not involved with that area when you create your designs?
>
> A: Typically from – we are, but I rely on – you know, we have material – more material experts that work on material[-]based things day in and day out. From a design standpoint we have limited materials we can utilize that are biocompatible and accepted by the FDA. And within that, we have parameters that we work with. And so from a design standpoint we're looking at the physical designs and the loading patterns, stress loading patterns on implants more so.
>
> Q: [Y]ou have read [Plaintiffs' expert] Mr. Coleman's deposition, correct?
>
> A: That's correct.
>
> Q: And you have read his original expert report, as well as his supplemental report?
>
> A: That's correct.
>
> Q: Do you feel as if you're qualified in the field of metallurgical engineering to do the same type of testing that Mr. Coleman did prior to writing his supplemental report?
>
> A: It's been a long time since I have put together reports of that nature and, you know – you know, I can review some of that but I – it's – I'm – it's fuzzy. That's not been my area of expertise over the last 10, 15 years. I'm knowledgeable in the field but not necessarily an expert in that field.

(Kelman Dep. at 68-69.)

Taken in context, it is clear that Kelman is referring to being "fuzzy" in the field of conducting destructive testing on devices, not the field of metallurgy as a whole. As Defendant points out, Kelman did not perform the testing on Reed's failed device; rather, Kelman reviewed both Coleman's testing and the design specifications of the failed implant, as is clear from Kelman's deposition testimony. Kelman is qualified to offer his opinions in these areas, to the extent his conclusions lie within the scope of his Rule 26 report, deposition testimony, and admissible portions of his affidavit.

2. Plaintiffs' Motion to Strike Kelman's Affidavit of August 14, 2007

Plaintiffs specifically object to the inclusion of ¶¶ 12, 13, 17, 19-22, and 24-29 in Kelman's August 14, 2007, affidavit as lying beyond the scope of Kelman's expert report and deposition testimony. (See Pls.' Mot. to Strike at 3-5.) Defendant responds that although Kelman expressly declined to update his Rule 26 report (see Dkt. No. 38 Ex. 4), the statements in the affidavit are merely a summary of Kelman's expert report and deposition testimony as well as proper responses for Kelman's designation as Defendant's Fed. R. Civ. P. 30(b)(6) designee.[15] (See Letter, Def.'s Resp. to Mot. to Strike Ex. 6.)

Having reviewed the disputed paragraphs, it is clear that one of the disputed paragraphs does contain additional information that was subject to supplementation under Rule 26(e)(1). Specifically, ¶ 29 of Kelman's affidavit criticizes the standard set forth by Plaintiffs' expert and speculates in detail as to the dire consequences such a standard would produce:

> [Plaintiffs' expert] Mr. Coleman states that "you've got to design it so that the worst case scenario can be handled by the device." Mr. Coleman sets the bar higher than [the] current state of biomedical science can reach. If that was [indeed] the standard for the design of primary and revision protheses [sic] for hip arthroplasty, there would be no such devices on the market. Mr. Reed would have been sentenced to life in a wheelchair at age 30, and all the tens of thousands of patients who have received the benefit of years of activity and pain relief from hip prostheses would have been denied [the benefit].

[15] Under Rule 30(b)(6), when a party names a corporation as a deponent, the corporation "shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify." The company's Rule 30(b)(6) designee(s) "shall testify as to matters known or reasonably available to the organization."

While it is true, as Defendant notes, that Kelman did generally critique Plaintiffs' expert's testing methods during his deposition testimony, this paragraph injects previously undisclosed opinions and supposition that do not fall within the scope of Kelman's Rule 26 report, deposition testimony, or his Rule 30(b)(6) designation. Defendant has offered no substantial justification for the failure to supplement Kelman's report or his deposition testimony with these new conclusions, and Plaintiffs would be harmed by their admission. Paragraph 29 of Kelman's August 14, 2007, affidavit thus is stricken and shall not provide support for Defendant's motions, responses, or at hearings or trial. See Fed. R. Civ. P. 37(c)(1).

3. Plaintiffs' Motion to Strike Kelman's Affidavit of September 6, 2007

In a separate motion, Plaintiffs similarly seek to strike a supplemental affidavit of Kelman's submitted by Defendant and dated September 6, 2007. (See Pls.' Second Mot. to Strike, Dkt. No. 75; Def.'s Resp., Dkt. No. 63 Ex. 5.) Having reviewed Kelman's Rule 26 report, curriculum vitae, and his deposition testimony, it is clear that with the exception of ¶¶ 5-6, which are identical to ¶ 17 of Kelman's earlier affidavit, the sworn affidavit at issue consists almost exclusively of "additions or other changes" for which supplementation would have been required, see Fed. R. Civ. P. 26(e)(1). Defendant has offered no substantial justification for the failure to supplement Dr. Landon's report or his deposition testimony, and Plaintiffs would be harmed by the admission of the previously undisclosed opinions. Therefore, Kelman's affidavit dated September 6, 2007, is stricken. Kelman shall not be allowed to provide such testimony in support of Defendant's motions or responses, and the

affidavit will not be considered or admitted at hearings or at trial. See Fed. R. Civ. P. 37(c)(1).

IV. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

A. Standard

A motion for summary judgment should be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "An issue of fact is 'genuine' if the evidence allows a reasonable jury to resolve the issue either way and is 'material' when 'it is essential to the proper disposition of the claim.'" Haynes v. Level 3 Commc'ns, LLC, 456 F.3d 1215, 1219 (10th Cir. 2006) (citation omitted), cert. denied, 127 S. Ct. 1372 (2007).

The movant bears the initial burden of demonstrating the absence of material fact requiring judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). If the movant carries this initial burden, the nonmovant must then set forth "specific facts" outside the pleadings and admissible into evidence which would convince a rational trier of fact to find for the nonmovant. Fed. R. Civ. P. 56(e). These specific facts may be shown "by any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." Celotex, 477 U.S. at 324. "The burden is not an onerous one for the nonmoving party in each case, but does not at any point shift from the nonmovant to the district court." Adler v. Wal-Mart Stores, Inc., 144 F.3d 664, 672 (10th Cir. 1998). All facts and reasonable inferences therefrom are construed in the light most favorable to the

nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). Although the nonmoving party need not produce evidence at the summary judgment stage in a form that would be admissible at trial, the content or substance of such evidence must be admissible. Argo v. Blue Cross & Blue Shield of Kan., Inc., 452 F.3d 1193, 1199 (10th Cir. 2006) ("To determine whether genuine issues of material fact make a jury trial necessary, a court necessarily may consider only the evidence that would be available to the jury.").

B. Plaintiffs' Manufacturers' Products Liability Claim

Plaintiffs are suing Defendant for injuries allegedly sustained due to the implantation and subsequent failure of the size 13 Echelon Porous Bowed Femoral Component manufactured by Defendant and implanted into Reed's hip on January 30, 2001. Plaintiffs' theories of liability include manufacturers' products liability ("MPL"), failure to warn, and breach of express and implied warranties.[16] (See Compl., Dkt. No. 1, ¶¶ 5-6.) Defendant argues that there is no evidence creating a genuine issue of material fact on Plaintiffs' manufacturers' products liability claim and asserts the affirmative defense of unavoidably unsafe product. (Def.'s Mot. for Summ. J. at 15-21.)

The parties' dispute lies in what caused the Echelon implant implanted in Reed's right hip to fracture, necessitating its removal on October 10, 2005, after about four-and-one-half years of use. Plaintiffs argue that while reduced bone support may have contributed to the

[16] Defendant did not move for summary judgment on Plaintiffs' failure to warn and breach of warranties claims.

fatigue failure of the implant, the fracture was caused by a manufacturing and/or design defect in the device. Defendant, however, claims that the implant's failure was due to inadequate bone support around the implant due to Reed's bone condition of avascular necrosis.

In order to maintain an MPL claim against the manufacturer under Oklahoma law,[17] Plaintiffs must show: (1) the product was the cause of the injury; (2) the product was defective when it left the manufacturer's possession and control; and (3) the defect rendered the product unreasonably dangerous to an extent beyond which would be contemplated by the ordinary consumer who purchases the product. See Kirkland v. Gen. Motors Corp., 1974 OK 52, ¶¶ 26, 29-31, 521 P.2d 1353, 1362-63. The mere fact that a plaintiff was injured by a product does not raise any presumption of defectiveness in regards to that product. Id. ¶ 28, 521 P.2d at 1363. The Oklahoma Supreme Court's observation in Kirkland is instructive:

> The practicing lawyer identified with the Plaintiff will seldom be able to produce actual or absolute proof of the defect so necessary in manufacturers' products liability since this information in the final analysis is usually within the peculiar possession of the Defendant. . . . [M]ore than likely Plaintiff may be forced to rely on circumstances and proper inferences drawn therefrom in making his proof.

Kirkland, ¶ 34, 521 P.2d at 1363.

While Defendant claims that there is no genuine issue as to whether the hip implant was defective and Plaintiffs cannot establish this element of MPL, admissible testimony of

[17] The parties have not disputed that Oklahoma law would be applied to this federal diversity action.

Plaintiffs' metallurgical expert Coleman directly contradicts this claim. As discussed above, Coleman tested the failed device, and his expert reports concluded that the Echelon implant bore manufacturing defects in the form of microcracks and an advanced crack network; these "inherent flaws" caused premature fatigue failure. (Pls.' Resp. to Mot. for Summ. J. at 1; Coleman Supplemental Report at 6-7.) According to Coleman, "[f]ailure was caused by defects in the sintered coating/substrate interface, its likelihood enhanced by the unfavorable microstructure. On this basis the device is defective." (Coleman Supplemental Report at 7.)[18] Because Defendant has not demonstrated the absence of a genuine issue as to the existence of a defect in Reed's Echelon hip implant, Defendant is not entitled to judgment as a matter of law. Defendant's proffered affirmative defense of "unavoidably unsafe product" likewise must fail at the summary judgment stage, because such a defense is inapplicable when the disputed product suffers a defect of "faulty manufacturing or inadequate warnings." See Tansy v. Dacomed Corp., 1994 OK 146, ¶ 14, 890 P.2d 881, 886.

V. CONCLUSION

For the reasons set forth herein, Defendant's motion to exclude Plaintiffs' expert Mr. Coleman's testimony (Dkt. No. 55) is DENIED. Plaintiffs' motion to exclude the testimony of Defendant's experts Dr. Landon and Mr. Kelman (Dkt. No. 56) is DENIED. Plaintiffs' motion to strike Defendant's experts' affidavits (Dkt. No. 67) is GRANTED IN PART.

[18] Because the factual issue as to the presence of a manufacturing defect precludes summary judgment on Plaintiffs' MPL claim, the Court need not at this time make any findings regarding Plaintiffs' claim that the Echelon implant additionally suffered from a design defect.

Plaintiffs' second motion to strike Defendant's experts' affidavits (Dkt. No. 75) is GRANTED. Defendant's motion for summary judgment (Dkt. No. 60) is DENIED.

IT IS SO ORDERED this 7th day of November, 2007.

ROBIN J. CAUTHRON
United States District Judge